K120871 (1/2)

JUN - 7 2012

Summary of Safety and Effectiveness
External Fixation System Instrumentation
Smith & Nephew, Inc.

Contact Person and Address
Gino Rouss
Group Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
7135 Goodlett Farms Parkway
Memphis, Tennessee 38016
T (901) 399-6707

Date of Summary: March 19, 2012

Name of Device: Smith & Nephew, Inc. External Fixation Instrumentation
Common Name: Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:

21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener

Device Class: Class II
Panel Code: Orthopaedics/87
Predicate Devices:

Richards External Fixation System (K870961);
Richards Titanium Half Pin (K920024);
Hex-Field Fixator (K953397);
Ilizarov External Fixation System (K962808);
Compass Universal Hinge (K970713);
Heidelberg External Fixator (K970751)
Taylor Spatial Frame External Fixation System (K970748);
S&N External Fixation System (K994143);
Jet-X TiN Coated Half Pins (K023134);
Jet-X HA Coated Half Pins (K023921);
External Fixation Systems (K031181);
Modification to Jet-X HA Coated Half Pins (K033289);
Jet-X Bar Clamps and Pin Clamps-Non-Magnetic/MR Safe (K042312);
Ilizarov Pulley System (K042436);
Jet-X Bar System Clamps, Bars, and Posts- MR Safe (K072212);
Smith and Nephew Rail System (K090926);
Smith and Nephew Circular Fixation System (K093047);
Smith and Nephew Spatialframe V4.1 Web-Based Software (K110069)

Device Description

Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. External Fixation Instrumentation. The subject devices are accessory devices and are intended to be used to assist in the implantation of the Smith & Nephew External Fixation Systems and their cleared

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Indications for Use. Smith & Nephew External Fixation Instruments can be organized into instrument families which are categorized as follows: Tightening/Insertion, Alignment, Guides, and Drills.

Intended Use

External Fixation Systems

1. Post-Traumatic joint contracture which has resulted in loss of range of motion (not applicable for Smith & Nephew Rail System)
2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
3. Open and closed fracture fixation
4. Pseudoarthrosis of long bones
5. Limb lengthening by epiphyseal or metaphyseal distraction (not applicable for COMPASS Universal Hinge or JET-X Fixator)
6. Correction of bony or soft tissue deformities (not applicable for COMPASS Universal Hinge)
7. Correction of segmental bony or soft tissue defects
8. Joint arthrodesis (not applicable for Smith & Nephew Rail System)
9. Infected fractures or nonunions
10. Mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius (not applicable for Smith & Nephew Rail System)
11. Calandruccio devices are indicated for arthrodesis of the ankle or subtalar joints. As well as some select fractures, nonunion, or osteotomy of the distal tibia; and acute transverse fractures or nonunion of the distal tibia (not applicable for Smith & Nephew Rail System)

Substantial Equivalence Information

The device specific instruments associated with the implant devices with which they are used are considered substantially equivalent to previously cleared device specific instruments in that both subject and predicate instruments:

- Share the same raw materials;
- Are manufactured though the same processes;
- Utilize the same sterilization procedures; and
- Have similar nature of body contact

The Smith and Nephew External Fixation Instrumentation are similar in design and function to competing plate and screw surgical instrumentation on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 7 2012

Smith & Nephew, Incorporated
% Mr. Gino Rouss
Group Manager, Regulatory Affairs
1450 Brooks Road
Memphis, Tennessee 38116

Re: K120871
Trade/Device Name: Smith & Nephew, Incorporated. External Fixation Instrumentation
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: KTT, JDW, LXT, OSN
Dated: March 19, 2012
Received: March 22, 2012

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120871

Device Name: Smith & Nephew, Inc. External Fixation Systems
Indications for Use:

The Smith & Nephew, Inc. External Fixation Instrumentation is intended for use in:

1. Post-Traumatic joint contracture which has resulted in loss of range of motion (not applicable for Smith & Nephew Rail System)
2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
3. Open and closed fracture fixation
4. Pseudoarthrosis of long bones
5. Limb lengthening by epiphyseal or metaphyseal distraction (not applicable for COMPASS Universal Hinge or JET-X Fixator)
6. Correction of bony or soft tissue deformities (not applicable for COMPASS Universal Hinge) .
7. Correction of segmental bony or soft tissue defects
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Prescription Use			Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	X	AND/OR	(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120871